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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/701,278	08/22/1996	DAVID J. ANDERSON	A-63770-1/RF	5313

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	38

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/701,278	Anderson et al
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 29, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-7* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-7* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 04/29/02 has been entered.

2. The rejection of claims 1-2 & 4-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing recite proper antecedent basis is withdrawn due to the amendment of the claims.

3. Applicant's arguments filed 04/29/02 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper Nos. 26, 29, 33 and 36 and as follows.

Applicants argue on pages 3-5 of the response *Brooktree Corp v. Advanced Micro Devices, Inc., In re Brana, In re Gazave* and *In re Wands.* However, *In re Wands* is case law for enablement and not for utility; thereby, being moot. Applicants then argue that "these novel

homeodomain proteins can be used to isolate sensory neurons". However, in contrast to Applicants' assertions, no where on page 31 of the specification is such an utility stated. Moreover, "expression" is not equivalent to "function"; especially when *many* proteins, or DNAs that encode such, reasonably are expressed in sensory neurons (i.e., as it especially relates to the genus of hybridization products claimed); thereby, still not being "specific", by definition. Further, as previously made of record, note that the claims are not limited to the preferred and described DRG11 polynucleotide sequence of SEQ ID NO:1 (i.e., as it relates to claims 1, 2 & 5-7), even if the function of DRG11 itself is later discovered. As previously made of record, the court in *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]". Therefore, as extensively made of record, because no known nor described function existed for the DRG11 protein of SEQ ID NO:2, or for polynucleotides that encoded such, at the time of filing the instant invention, no "specific" utility exists, by definition.

Second, as previously made of record, further experimentation is still necessary at the time of filing the instant invention to attribute a "real world" utility to the claimed polynucleotides (i.e., as it relates to establishing a "substantial" utility), because no assayable function for the DRG11 of the instant invention is known in the art nor adequately described within the instant specification, and because no disease state, etc. is known in the art nor specifically described within the specification; in which an invitation to discover such

alternatively supports the rejection that no "substantial" utility exists at the time of filing Applicants' invention. Again, the rationale is that one would expect that a limited number of dysfunctional genes would be useful as markers for diseases, versus a generalized "molecular marker to identify neurons in the peripheral sensory lineage" or the generalized "markers... [that may be useful] to obtain or isolate pools of such [peripheral sensory] neurons". Thus, Applicants' arguments remain not persuasive, for the reasons made of record.

Accordingly, the instant situation is analogous to that decided by the courts in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. In particular, the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

6. Claims 1-2 & 4-7 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper Nos: 26, 29 & 36.

7. Claims 1 & 5-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 26, 29, 33 & 36, and as follows.

In contrast to Applicants' assertions on page 6-8 of the response, Applicant continues to mischaracterize the record, as it relates to the DRG11 protein of the instant invention being a "homeodomain *transcription factor*". In contrast, the instant invention describes DRG11 as being some "homeodomain protein... in the PHD family", which has no known nor disclosed "regulatory" function, and which, therefore, would reasonably be involved in some unknown and undisclosed protein-protein interaction, versus the protein-DNA interactions that characterize "*transcription factors*". In other words, no where in the instant specification is it contemplated that DRG11 is a "homeodomain *transcription factor*". Alternatively, the issue remains that one of ordinary skill in the art cannot reasonably visualize what generic nucleic acid sequences are

specifically encompassed by the current claims (i.e., by SEQ ID NO; as it relates to the undescribed hybridization products claimed); nor could one reasonably visualize what constitutes generic sequences encompassed by these claims based solely on the written description of the *single* cDNA sequence of SEQ ID NO:1. In other words, an invitation for others to discover such does not address the pending rejection. Importantly, because no known nor disclosed function exists for the encoded DRG11 protein(s) of the instant invention, what constitutes a functional allelic variant (i.e., as it relates to the hybridization products claimed) cannot be reasonably determined at the time of filing Applicants' invention, for the reasons made of record.

Accordingly, *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) held that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". In addition, *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) then held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single species of the encoded rat DRG11 protein of SEQ ID NO:2, and its corresponding DNA of SEQ ID NO:1, has been described in the instant specification. *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) further makes clear that:

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a*

substantial portion of the genus [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

In contrast, an invitation for others to discover a representative number of species with a "known or disclosed correlation between function and structure" merely based on an invitation that others can "determine [such]... by comparing sequence homology and expression patterns" does not address the rejection made of record, because only no assayable function is known in the art nor described within the specification for discovering other members of the claimed genus. Therefore, in contrast to Applicants' arguments, Applicants are clearly not in possession of the claimed genus at the time of filing Applicants' invention.

Applicant is again directed toward the Revised Interim Written Description and Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999. See especially, Examples 11 & 17.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
July 17, 2002

GARY L. KUNZ
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